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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/185,908	11/03/98	BLASCHUK	0 1000086.49

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HM22/0308

EXAMINER
DECLoux, A

ART UNIT	PAPER NUMBER
1644	9

DATE MAILED:

03/08/00

Please find below and/or attached an Office communication concerning this application or
proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/185,908

Applicant(s)

Blaschuck et al

Examiner

DeCloux, Amy

Group Art Unit

1644



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-63 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-63 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-20, 27-43, 46-49, 52-55, and 58-61, drawn to a peptide cell adhesion modulating agent, classified in Class 530, subclasses 326-330, Class 514, subclasses 9, 11-18.

II. Claims 21-23, 44, 50, 56 and 62 drawn to a polynucleotide encoding a modulating agent, a vector and a host cell, classified in Class 536, subclass 23.5, Class 435, subclasses 320.1 and 252.3,

III. Claims 24, 27-39, 45, 51, 57 and 63, drawn to a modulating agent comprising an antibody that binds to a claudin CAR sequence, classified in Class 424, subclasses 134.1 and 139.1 and Class 530, subclass 387.3 and 387.9,

IV. Claims 25-39, drawn to a mimetic of claudin CAR sequence, classified in Class 514, subclass 2 and Class 530, subclass 402.

Note, claims 27-39 have been included in multiple groups, due to the multiple dependency of these claims.

2. Groups I-IV are unique products. They differ with respect to their physicochemical properties and are therefore patentably distinct.

3. If Group I is elected, the applicant is further required under 35 U.S.C. 121 to elect a **specific discrete sequence with a defined length and with each residue being represented by one amino acid residue**: from the group from SEQ ID NO:1 (claudin) as recited in Claims 2-4 and 40-41 and 46 and 52 and 58.

4. Additionally, If Group I is elected, the applicant is further required to elect a **second** modulating agent which is a **specific cyclic peptide where X₁, X₂, Y₁, Y₂, Z₁ and Z₂ are each defined as a single, integer with a defined length of residues, with each residue being represented by one specific residue, and the linkage between Y₁ and Y₂ defined as a specific type bond** as recited in Claims 8-20, 42-43, 49, 55 and 61.

5. Additionally, If Group I is elected, the applicant is further required to elect a **third specific adhesion molecule other than claudin**, such as a specific integrin etc. as recited in Claims 34 and 39.

6. Additionally, If Group I or III or IV is elected, the applicant is further required to

elect a **specific entity to which the recited modulating agents are linked** ie a drug, detectable marker, targeting agent or support material, as recited in Claims 27-30. If a **support material** is elected, then applicant is further required to elect a **specific type of support material**, ie polymeric matrix, plastic dishes etc. as recited in Claims 27-32.

7. Additionally, If Group II is elected, the applicant is further required to elect **A) a specific polynucleotide** recited in **Claim 21** that encodes a specific modulating reagent **recited in claims 1-4, B) and also to elect a specific polynucleotide** recited in **Claim 44** that encodes a specific modulating reagent **recited in Claim 40, C) and also to elect a specific polynucleotide** recited in **Claim 50** that encodes a specific modulating reagent **recited in Claim 46, D) and also to elect a specific polynucleotide** recited in **Claim 56** that encodes a specific modulating reagent **recited in Claim 52, E) and also to elect a specific polynucleotide** recited in **Claim 62** that encodes a specific modulating reagent **recited in Claim 58**.

8. If Group III is elected, the applicant is further required to elect an antibody that binds to a **specific discrete amino acid sequence** from SEQ ID No: 1 that will be examined in addition to an examination of antibodies that bind to SEQ ID Nos:34, 42, 50 and 58 as recited in claims 45, 51, 57 and 63.

9. If Group IV is elected, the applicant is further required to elect a mimetic of a claudin CAR sequence that is a **specific discrete amino acid sequence** from SEQ ID No: 1 that comprises at least **three** consecutive amino acid residues of a claudin CAR sequence as recited in Claim 25.

10. If Group IV is elected, the applicant is further required to elect a mimetic of a claudin CAR sequence that is a **specific discrete amino acid sequence** from SEQ ID No: 1 that comprises at least **five** consecutive amino acid residues of a claudin CAR sequence as recited in Claim 26.

11. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Art Unit 1644

13. The following claim(s) are generic: claims 1-8, 12, 14, 21, 24-26, 33, 35, 40, 42, 46, 48, 52, 55, 56, 58, 60 and 62.

The species are distinct each from the other for the following reasons:

A) The recited agents (peptide based cell adhesion modulating agents, polynucleotides, antibodies and mimetics) have different biochemical characteristics, structure and functions.

B) The recited sequences have different biochemical characteristics, structure and functions, and different searches are required in the sequence databases.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. Or a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

17. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
March 3, 2000

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/644